



February 16, 1998

Center Food Safety & Applied Nutrition FB8 U.S.F.D.A. Room 2804 200 C Street S.W. Washington D.C. 20204



Re: Structure & Function Statement

To whom it may concern,

Fitness Labs has introduced a new Dietary Supplement product on February 10, 1998. We wish to inform you that our product displays on a side panel of the label a Structure and Function Statement, followed by a FDA disclaimer. The product is Creatine and the statement is contained in the following panel:

Creatine is Ideal for Athletes

Creatine is a natural substance that is synthesized in the body from three amino acids, arginine, glycine and methionine. It is also found naturally in foods such as red meat. A 16 oz. steak contains about 2g of creatine.

In the body, creatine helps to regenerate ADP (spent energy) back into ATP for increased energy output involving short, intense bursts of energy. Short term supplementation of creatine monohydrate has been shown to significantly increase muscular performance. It may help athletes workout at a higher intensity during resistance exercise. A resulting greater training stimulus over time may result in enhanced physiologic adaptations.*

- * These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.
- ¹ J.S. Volek, W.J. Kraemer, et al., "Creatine supplementation enhances muscular performance during high-intensity resistance exercise." *J Am Diet Assoc.* (1997) 97:765-770.

A copy of the label is enclosed. Thank you for your time.

Sincerely,

Hackyn Mine

Kathryn Moore

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P.O. Box 3896 Torrance, CA 90510-3896 Phone (310) 325-0075 Fax (310) 325-5559



Stir I heaping scoop (5 grams) of powder into 8 fluid ounces of water or juice (or other high carbohydrate meal or drink).

When to use:

V Loading Phase (day Lin 2) Take I heaping scoop (5 grams) of creating 3 to 5 times daily for 7 consecutive days.

 Maintenance Phase (day & and beyond): Take I heaping scoop (5 grams) of creatine 1 to 2 times daily. Drink plenty of water

when supplementing with creatine to avoid denydration approximately i gallon a day).

FITNESS LABS

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> This Fitness Labs Product contains only the finest Laboratory Tested ingredients. Their Potency, Purity and Quality are Guaranteed.

guality, ultra premium grade creatine monohydrate with nothing added

Pack some

power into

your training

Highest

Mixes easily into fluids

> Scoop enclosed

Creatine

379 7 3 E

HPLC tested, pure Creatine Monohydrate powder

Dietary Supplement

NET WT 1000 grams (2 LB 2 OZ)

Serving Size: 1 Scoop (5-3) Servings Per Container: 200

Ideal for

athletes

engaged in

sports requiring quick, explosive

movements!

This white,

crystalline

powder is

virtually

tasteless and

odorless.

1 Scoop ≈5g

5g Creatine

Amount Per Serving

Creatine Monohydrate 5g Daily Value not established.

Supplement F

Ingredients: 99% pure. pharmaceutical grade, creating monohydrate, tested by the

Contains no fillers, additives, colors, flavors, sugars or sweeteners.

Developed by and manufactured for:

Fitness Labs" Nutrition Corporation P.O. Box 3896 • Torrance, CA 90510-3896 To reorder, call:

(800) 407-8222 or (310) 325-0075

www.fitnesslabs.com

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Storage: Store in cool, dry place.

Caution: Keep out of reach of children. This product is not intended to diagnose, treat, cure or prevent any disease. Consult your physician before beginning any exercise or diet program. This product is not to be used if you suffer from diabetes. kidney malfunction, bladder problems, or suspected heart disease. The product is not to be used by women during pregnancy or lactation.



